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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,037	01/22/2004	Robert J. Schwartz	HO-P02659US1	8488
26271	7590	03/17/2008	EXAMINER	
FULBRIGHT & JAWORSKI, LLP			LONG, SCOTT	
1301 MCKINNEY				
SUITE 5100				
HOUSTON, TX 77010-3095				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/763,037	Applicant(s) SCHWARTZ ET AL.	
	Examiner SCOTT D. LONG	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,6 and 8-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,6 and 8-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/18/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner acknowledges receipt of Applicant's Remarks and Claim amendments, filed on 18 December 2007.

Claim Status

Claim 9 is amended. Claims 1-4, 7, and 16-41 are cancelled. Claims 5-6 and 8-15 are under current examination.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 18 December 2007 consisting of 1 sheet(s) is/are in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

Priority

This application claims benefit from provisional U.S. Application No. 60/441,668 (filed 01/22/2003). The instant application has been granted the benefit date, 22 January 2003, from the application 60/441,668.

Response to Arguments - Claim Objections

Applicant's arguments, see pages 4-5 and Claim amendments, filed 18 December 2007, with respect to claims 9 and 15 have been fully considered and are persuasive.

Claim 9 has been amended and satisfactorily addresses the examiner's concerns. Therefore, the objection to claim 9 is hereby withdrawn.

The applicant has satisfactorily explained how claim 15 further limits claim 5. The applicant cited the specification's definition of cardiac failure as being a type of cardiac disease. Therefore, the examiner hereby withdraws the objection to claim 15.

Response to Arguments - Claim Rejections 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-6 and 8-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Drewett et al. (Journal of Biological Chemistry. 2001. Vol.276; No.36: 33444-33451) in view of Narula et al. (PNAS. July 1999. Col.96: 8144-8149) for the reasons of record.

Applicant's arguments have been fully considered but are not persuasive.

Applicants traverse the instant rejection on the following grounds:

The applicant implies that the examiner has not established a case of *prima facie* obviousness because he has not explained the reasons why one of ordinary skill in the art would have derived the claimed subject matter and why one of ordinary skill in the art would have a reasonable expectation of success. In particular, the applicant states "one of ordinary skill in the art would have no expectation that these results would be similar in any cell other than BJAB....The examiner has not indicated why a person of ordinary skill in the art would have any reasonable expectation that the cleavage and apoptosis in BJAB cells would occur in any other cell type" (Remarks, page 6, paragraph 1). Contrary to the applicant's assertion, the examiner provided a reasoned explanation of why a skilled artisan would have combined the teachings of Drewett and Narula. This reasoning follows:

Taken together, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to combine the teachings of Drewett et al. with Narula et al. to develop a method of diagnosing cardiac disease in an individual comprising the step of identifying cleavage of SRF in at least one cell from a sample from said individual. The person of ordinary skill in the art would have been motivated to make those modifications because both references indicate a link between apoptosis and disease states. Narula et al. indicate the relationship between apoptosis and heart failure, while Drewett et al. describe the relationship between Serum Response Factor (SRF) cleavage and apoptosis. All of the details of the claimed invention are taught by

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the references, including immunoblotting with antibodies specific for N- or C-termini of SRF and comparisons of normal cardiac tissue and tissue from patients with end-stage cardiac failure. The skilled artisan would have had a reasonable expectation of success in combining the teachings of Drewett et al. and Narula et al. because the methods and reagents are well characterized and commercially available. Furthermore, both references adequately explain the relationship of apoptosis to disease and methodologies used in their biochemical analyses. Therefore the examiner finds the applicant's argument unpersuasive.

Regarding the applicant's suggestion that there is "no reasonable expectation that the cleavage and apoptosis in BJAB cells would occur in any other cell type," the examiner points out that Drewett et al. teach "These observations suggest that in NIH3T3 cells SRF is cleaved in half under certain conditions" (page 33445, col.2, last parag.) and "NIH3T3 cells were found to enter apoptosis" in response to accumulation of cleaved SRF fragments (page 33446, col.1, lines 1-12). Therefore, the examiner believes that Drewett has demonstrated that cleavage of SRF is critical to induction of apoptosis regardless of the cells in which the SRF is cleaved and the examiner believes that Drewett has demonstrated that SRF is cleaved in NIH3T3 cells. Therefore the examiner finds the applicant's argument unpersuasive.

In addition, the applicant has provided prior art (Davis et al. and Chang et al.) published near the time of the art cited by the examiner in his 35 USC 103 rejection and near the time of the instant application within which the applicant asserts "provide evidence that one of skill in the art, armed with the knowledge available in the art at the

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time of filing, would have believed alternatively spliced SRF fragments were associated with cardiac disease and would not have expected the cleavage of SRF and apoptosis in BJAB cells as taught in Drewett et al. to be applicable to cardiac cells." (Remarks, page 6, parag.2). Contrary to the applicant's assertion, Drewett et al. describe two possible mechanisms for the apoptotic activity of SRF fragments, "Two different mechanisms can be envisaged to account for these observations...cleavage fragment of SRF...[and] alternate splicing at exon 5, has also been shown to...act as an inhibitor of SRF function" (Drewett, page 33450, col.1, first full paragraph). Therefore, the examiner disagrees with the characterization of the prior art. The examiner believes at least Drewett et al. understood that there were other possible mechanisms for the production of SRF fragments than alternative splicing, in particular cleavage of SRF. It is possible that Davis and Chang were either unaware of the teachings of Drewett or that they were trying to promote their "pet theories." Ultimately, at least one group of researchers (Drewett et al.) conceived of the production of SRF fragments and their relationship to apoptosis prior to the filing of the instant application. Therefore the examiner finds the applicant's argument unpersuasive.

The applicant has rearranged the claim set by moving the limitations of cancelled claim 7 into claims 5, thereby narrowing the scope of the instant claims to apply to cardiac cells from a patient sample. In addition, claim 9 has been amended to compare levels of cleaved SRF from an individual suspected of having cardiac failure. Narula et al. teaches taking samples of myocardial tissue from patients with heart failure

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(particularly, page 8145). Therefore, the examiner believes that the teachings of Drewett and Narula are obvious over the amended claims for the reasons of record.

Therefore, the examiner hereby maintains the rejection of claims 5-6 and 8-15 under 35 U.S.C. 103(a) as being unpatentable over Drewett et al. in view of Narula et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**.

The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SDL/ Scott Long
Patent Examiner, Art Unit 1633

/Janet L. Epps-Ford/
Primary Examiner, Art Unit 1633